



Viralgen Partners with Elaaj Bio to Advance Gene Therapy Program for CDKL5 Deïnciency Disorder

Descrizione

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Collaboration leverages AAV manufacturing expertise to advance a preclinical-stage gene therapy program for a rare pediatric neurological disorder.

SAN SEBASTIÁN, Spain and LONDON, May 5, 2026 /PRNewswire/ â?? Viralgen, a leading contract development and manufacturing organization (CDMO) specializing in recombinant adeno-associated virus (rAAV) gene therapies, announced today a partnership with Elaaj Bio, a biotechnology company focused on development of transformative treatments for CDKL5 Deïnciency Disorder (CDD). Elaaj Bio is a wholly owned subsidiary of the Loulou Foundation, a private non-proït foundation dedicated to the development and research of therapeutics for CDD. The collaboration, to advance an investigational CDKL5 gene therapy, brings together complementary expertise across development and manufacturing services for adeno-associated virus (AAV) vectors to support advancement of the program toward clinical development.

As part of the collaboration, Viralgen will leverage its expertise in AAV vector manufacturing to support key development activities, including process development and optimization, manufacturing across multiple scales, and analytical characterization and quality control. Initial development work has been successfully completed, demonstrating technical feasibility of the manufacturing approach, and ongoing activities are focused on process scale-up, including the preparation of larger-scale batches.

â??Collaborations like this are essential to advancing complex gene therapy programs, particularly in rare pediatric diseases where the need for new therapies and innovations remains high,â? said Jimmy Vanhove, Chief Executive Officer at Viralgen. â??By working with Elaaj Bio and the Loulou Foundation, weâ??re uniting complementary strengths in development and manufacturing to help accelerate ELJ-101 toward clinical development.â?•

CDKL5 Deïnciency Disorder (CDD) is a rare and severe developmental and epileptic encephalopathy caused by alterations in the CDKL5 gene. The condition is characterized by early-onset seizures and

significant neurodevelopmental impairment, with a profound impact on affected individuals and their families. The

investigational gene therapy program is being developed to target the underlying genetic cause of the disease.

Elaaj Bio and the Loulou Foundation are mission-driven: everything we do is focused on finding treatments for CDD," said Russ Addis, Chief of Pipeline Strategy and Head of Genetic Medicine at the Loulou Foundation. "The Viralgen team have embraced that mission; we have great hopes that this collaboration will result in an effective gene therapy that treats the underlying cause of CDKL5 Deficiency."

The teams plan to initiate the first clinical trial for this program, ELJ-101, in early 2027. Current efforts are focused on scaling manufacturing processes to support future clinical development.

About Viralgen:

Viralgen is a leading Contract Development and Manufacturing Organization (CDMO) specializing exclusively in adeno-associated virus (AAV)-based gene therapies. Founded in 2017 as a subsidiary of AskBio, Inc. within the Bayer AG group, Viralgen delivers end-to-end support from early development to large-scale commercial manufacturing. Leveraging their proprietary Pro10 suspension cell line and Aava manufacturing platform, Viralgen achieves industry-leading, high-yield, scalable manufacturing across all AAV serotypes. Located in San Sebastian, Spain, its state-of-the-art facility features three cGMP suites with 2,000-liter capacities each, certified by the AEMPS/EMA, and integrates services including plasmid production, process optimization, fill-finish, and in-house QC testing. With over 1,500 AAV batches produced, Viralgen provides reliable, efficient solutions bringing life-changing gene therapies to patients with greater speed and consistency. Learn more at viralgen.com and follow us on LinkedIn.

About Elaaj Bio and the Loulou Foundation:

Elaaj Bio is a wholly owned subsidiary of the Loulou Foundation, a private non-profit UK foundation dedicated to advancing research into the understanding and development of therapeutics for CDKL5 deficiency disorder. The Foundation funds research projects at leading universities and institutes in the US and Europe, with a

total of 31 separate projects in 41 labs at 30 different institutions so far, enabling the focused research of over 120 scientists.

The Loulou Foundation also hosts the CDKL5 Forum, the annual conference which has become the flagship meeting for CDKL5 deficiency disorder basic and clinical science. Learn more at <http://www.louloufoundation.org> and <http://www.elaajbio.com>.

This press release contains forward-looking statements regarding the development of an investigational gene therapy program. These statements are subject to risks and uncertainties, including those related to research and development, manufacturing, and regulatory processes. The investigational therapy described herein has not been approved by the U.S. Food and Drug Administration or any other

regulatory authority.

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